

**REMARKS**

The present Office Action addresses claims 1-7, 10-19, 21-27, 29-33, and 35, however claims 2-5, 13-16, and 25 are withdrawn from consideration. Remaining claims 1, 6, 7, 10-12, 17-19, 21-24, 26, 27, 29-33, and 35 stand rejected.

Applicants thank Examiner Shaffer for extending the courtesy of a telephone interview to Applicants' undersigned representative on March 19, 2009. No agreement was reached.

**I. Amendments to the Claims**

Applicants amend claim 12 to clarify that the protrusions allow a spinal fixation element to extend into the *distal portion* of the cavity, as the claim previously only specified the cavity which was unclear. No new matter is added.

Applicants add new claim 36, which corresponds to claim 1 as previously amended in the Amendment filed on September 19, 2007. Applicants also add new claim 37, which recites the same language previously added to claim 1 in the Amendment filed on June 10, 2008. Accordingly, no new matter is added.

**II. Summary of Claimed Subject Matter**

Independent claim 1 recites a spinal anchoring device having a bone-engaging member adapted to engage bone and having a head formed thereon, a spinal fixation element, and a U-shaped receiver member having a distal cavity that movably seats the head of the bone-engaging member and the U-shaped receiver member having a proximal recess that seats the spinal fixation element. The cavity and the recess include an opening extending therebetween and defined by the U-shaped receiver member. The opening has a size that allows a portion of the spinal fixation element to extend into the distal cavity but prevents passage therethrough of the spinal fixation element seated in the proximal recess. Claim 1 also recites a fastening element adapted to mate to the U-shaped receiver member to lock the spinal fixation element relative to the U-shaped receiver member while allowing the U-shaped receiver member to move freely relative to the bone-engaging member. This type of anchoring device is hereinafter generally referred to as a *non-locking polyaxial bone screw*.

Independent claim 12 recites a spinal anchoring system that includes a spinal fixation element, and a spinal anchoring device having a bone-engaging member with a head formed thereon and a U-shaped receiver member having a cavity that freely movably seats the head of the bone-

engaging member in a distal portion of the cavity and that is configured to receive the spinal fixation element in a proximal portion of the cavity. The proximal and distal portions of the cavity are spaced apart by opposed protrusions defined by the U-shaped receiver member that allow a portion of a spinal fixation element to extend into the distal portion of the cavity but prevent contact between the bone-engaging member and the spinal fixation element. Claim 12 further recites a fastening element receivable within the U-shaped receiver member of the spinal anchoring device and being configured, when mated to the U-shaped receiver member, to lock the spinal fixation element to the spinal anchoring device while allowing free movement of the U-shaped receiver member relative to the bone-engaging member.

Independent claim 24 recites a method for correcting spinal deformities that includes implanting a plurality of anchoring devices into adjacent vertebrae in a spinal column, each anchoring device including a bone-engaging member that is fixedly attached to the vertebra and a U-shaped receiver member having a distal cavity that seats a head formed on the bone-engaging member such that the U-shaped receiver member is freely movable relative to the bone-engaging member and the vertebra; coupling a spinal fixation element to a proximal recess in the U-shaped receiver member on each anchoring device such that the fixation element extends between each of the adjacent vertebrae, the cavity and the recess of the U-shaped receiver member including an opening extending therebetween and defined by the U-shaped receiver member, the opening further having a size that allows a portion of a spinal fixation element to extend into the cavity but prevents passage of the spinal fixation element therethrough; and locking the spinal fixation element to the U-shaped receiver member on each anchoring device to maintain the adjacent vertebrae at a fixed distance relative to one another, the spinal fixation element being seated in the opening but prevented from contacting the bone-engaging member, thereby allowing free movement of each U-shaped receiver member relative to each bone-engaging member.

Independent claim 32 recites a spinal anchoring device that includes a bone screw having a head and a shank, a spinal fixation element, a U-shaped receiver member having a distal seat for receiving at least a portion of the head of the bone screw, a proximal seat formed on an internal surface thereof that receives the spinal fixation rod, and opposed protrusions that define an opening between the distal seat and the proximal seat that allows a portion of the spinal fixation element to extend into the distal seat but that prevents passage therethrough of the spinal fixation element seated in the proximal seat, and a fastening element adapted to mate to the U-shaped receiver member to

seat the spinal fixation rod in the proximal seat. The proximal seat is spaced a distance apart from the distal seat sufficient to allow polyaxial motion of the bone screw relative to the U-shaped receiver member upon seating of the spinal fixation rod in the proximal seat by the fastening element.

New independent claim 36 recites a spinal anchoring device having a bone-engaging member adapted to engage bone and having a head formed thereon, a U-shaped receiver member having a distal cavity that movably seats the head of the bone-engaging member and having a proximal recess that is adapted to seat a spinal fixation element, the cavity and the recess including an opening extending therebetween and having a size that prevents passage therethrough of a spinal fixation element seated in the proximal recess, and a fastening element adapted to mate to the U-shaped receiver member to lock a fixation element relative to the U-shaped receiver member while allowing the U-shaped receiver member to move freely relative to the bone-engaging member.

### III. Argument

#### A. The Rejection Of Claims 1, 6, 7, 10-12, 17-19, 21-24, 26, 27, 29-33, And 35 Pursuant To 35 U.S.C. §103(a) Over Parker, Biedermann, And Schlapfer Should Be Reversed

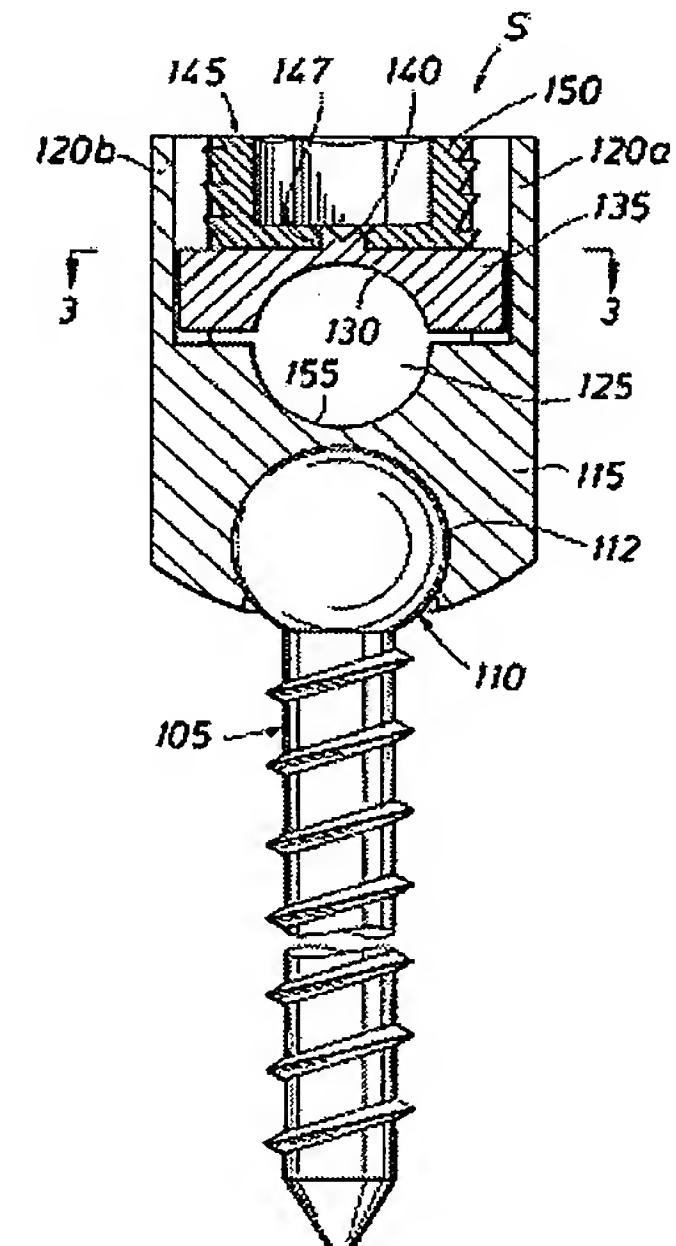
##### *1. The Examiner's Rejection And The Scope and Content Of The Prior Art*

Claims 1, 6, 7, 10-12, 17-19, 21-24, 26, 27, 29-33, and 35 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Application No. 2004/0260284 (“Parker”) in view of U.S. Application No. 2004/0049190 (“Biedermann”) and further in view of U.S. Patent No. 6,063,090 of Schlapfer (“Schlapfer”).

The Examiner argues that Parker discloses a device having a bone-engaging member (105) with a spherical head (110) formed thereon, a U-shaped receiver member (115) having a proximal recess/seat (155) that receives a spinal rod (200) and a distal cavity (112) that seats the head of the bone-engaging member (105), and a threaded set screw/fastener to mate with the receiver to lock the spinal rod in position while allowing free polyaxial movement of the bone-engaging member (105), as shown in Figure 1 reproduced herein.

The Examiner admits that Parkers fails to each an

**FIG. 1**



opening extending between the proximal recess (155) and distal cavity (112) where the opening is sized to prevent passage of a spinal fixation element as well as the opening having a size that allows a portion of the spinal fixation element to extend into the distal cavity.

The Examiner relies on Biedermann to teach a passageway (17) too small to allow the spinal rod to pass to sufficient to allow a screw driver to engage the bone-engaging member, as shown in Figures 3 and 4 reproduced below.

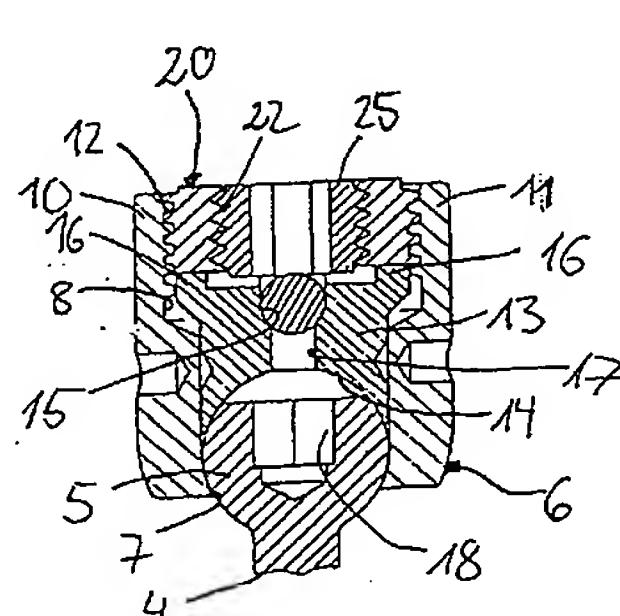


Fig.3

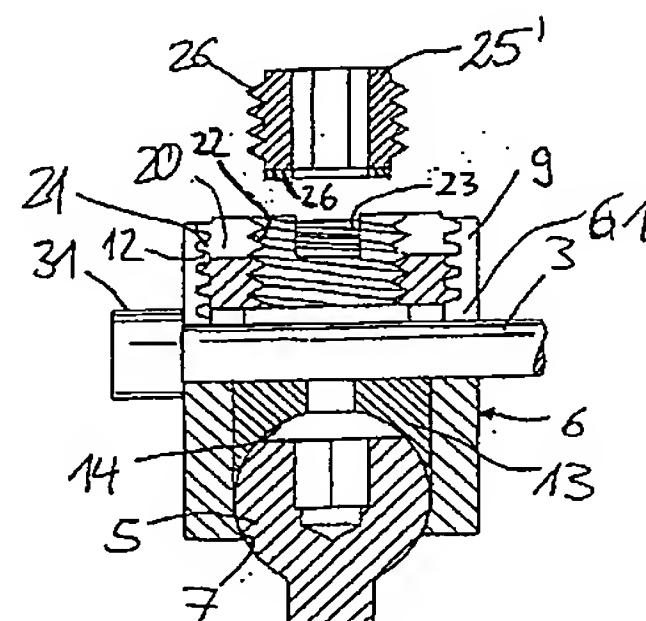


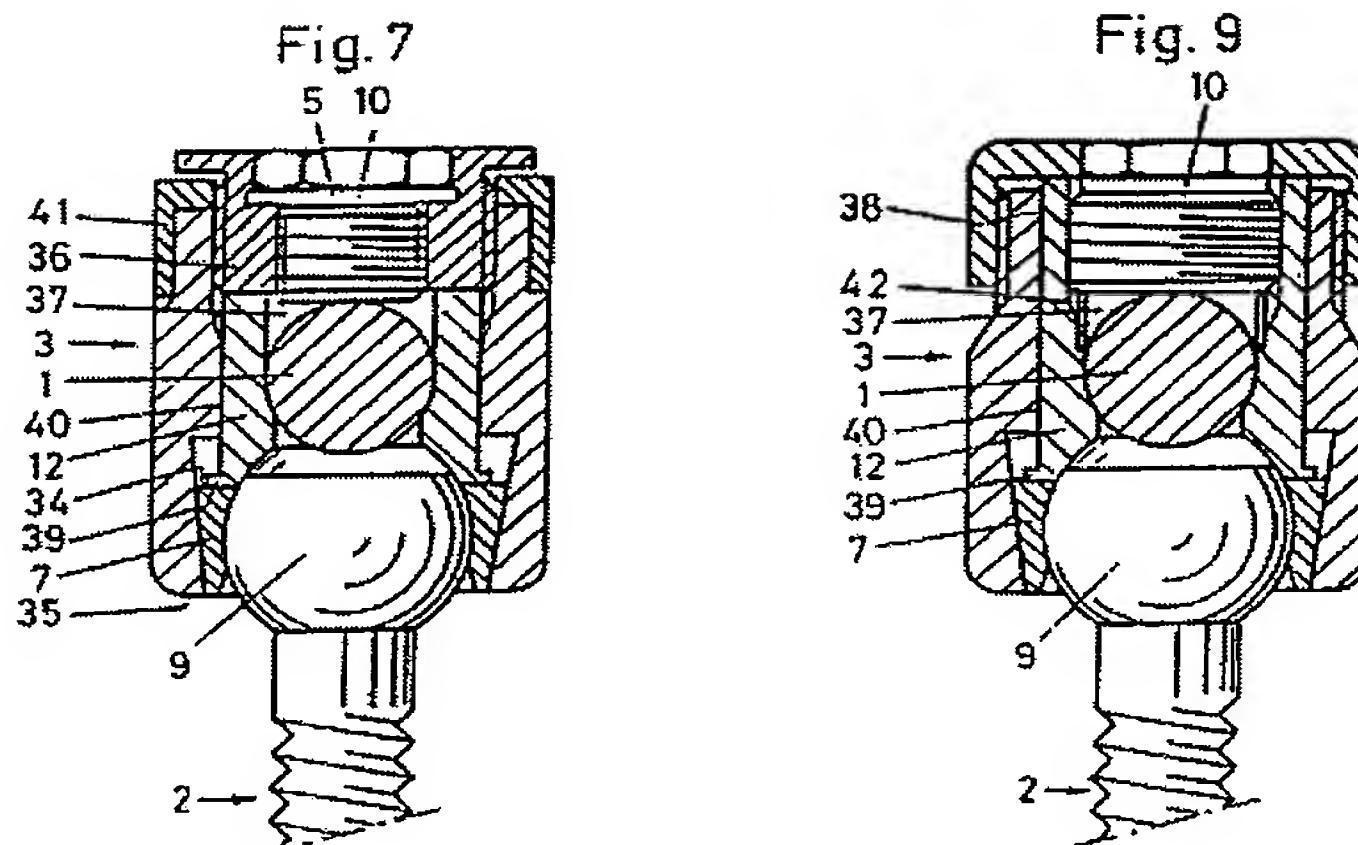
Fig.4

The Examiner argues that

[t]his allows the bone-engaging member to be pre-assembled to the U-shaped receiver member and ready to accept the spinal rod immediately after fixation in the bone without any intermediate steps thereby minimizing the complexity and duration of surgery. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide for a small passageway between the proximal recess and distal cavity of Parker in order to allow for the components to be pre-assembled thereby reducing surgical complexity and duration.

December 29, 2008 Office Action, p. 3.

The Examiner relies on Schlapfer to teach an arrangement such that the spinal rod (1) is partially seated within the distal cavity which houses a flat-topped (9) polyaxial screw (2), as shown in Figures 7 and 9 reproduced below.



The Examiner argues that

[i]t would have been obvious to one having ordinary skill in the art at the time of [the] invention to substitute a hole design of Schlapfer which allows the spinal rod to partially extend into the distal cavity and to substitute a fully-round headed polyaxial screw with a flat-topped polyaxial screw in order to provide an equivalent means of supporting a spinal rod on a polyaxial screw with predictable results.

*Id.* at pp. 3-4.

**2. The Combination of Parker, Biedermann, and Schlapfer does not Render Obvious Claims 1, 6, 7, 10-11, 24, 26, 27, 29-33, And 35**

The Examiner's rejection should be reversed because Parker, in addition to the deficiencies admitted by the Examiner, further fails to teach a non-locking polyaxial bone screw, i.e., a device in which the spinal fixation element can be locked relative to the U-shaped receiver member while allowing the U-shaped receiver member to move freely relative to the bone-engaging member, as required by independent claims 1 and 24. Moreover, even if it is assumed that Parker teaches a non-locking polyaxial bone screw, Biedermann does not remedy the deficiencies of Parker as Biedermann likewise fails to teach an opening defined by the receiver member. It also would not have been obvious to modify Parker to include an opening, as purportedly taught by Biedermann, and it would not have been obvious to modify Parker to include a flat-headed screw and to alter the screw such that the spinal fixation element extends into a distal cavity, as purportedly taught by Schlapfer.

a. *Parker fails to teach a Non-Locking Polyaxial Bone Screw*

The Examiner relies on Figures 1 and 2 of Parker to teach a polyaxial bone screw that can receive and lock a spinal fixation element, i.e., rod (200), relative to the receiver head (115) while still allowing free movement of the receiver head (115) relative to a bone-engaging member, i.e., bone screw (105). Applicants disagree. The Examiner's interpretation is incorrect based on the teachings of Parker, and moreover cannot be applied because such an interpretation would result in Parker's device being not enabled.

At the outset, while a claimed invention may be anticipated or rendered obvious by a drawing in a reference regardless of whether the drawing disclosure was accidental or intentional, a drawing is only available as a reference for all that it teaches a person of ordinary skill in the art. See *In re Meng*, 492 F.2d 843 (C.C.P.A. 1974). The drawings must be evaluated for what they reasonable suggest to a person having ordinary skill in the art. See *In re Wagner*, 20 C.C.P.A. 985, 987 (C.C.P.A. 1933). Here, Parker does not reasonably suggest a non-locking polyaxial bone screw. To the contrary, the specification of Parker suggests a construct in which the entire assembly is locked to prevent movement of both the rod and the receiver head relative to the bone screw. In particular, in the Background of the Invention section, Parker describes a typical pedicle screw, explaining that

[t]he screw shank typically extends through the bottom of the screw head and is held in place in a polyaxial joint that allows for flexibility to adapt to the desired position of the vertebra. The closure cap is then typically inserted down on top of the rod and threaded into the receiver or head, locking the rod down tightly to the receiver as well as locking down the polyaxial joint between the receiver and the screw shank.

Parker at para. [0004] (emphasis added). Parker thus makes it clear that typical pedicle screws lock the entire construct, including locking the receiver head relative to the bone screw. Parker improves upon the typical pedicle screw by providing an anti-splaying feature located in the proximal portion of the receiver head. Parker does not teach or even suggest any configuration in which the receiver head remains free to move relative to the bone screw after the rod is locked within the receiver head. Parker further states that "FIG. 6 illustrates the use of pedicle screws S with a common rod 200 locking multiple vertebra in a desired alignment." If the pedicle screw S is interpreted to have a non-locking polyaxial bone screw, as asserted by the Examiner, then the screw could not lock multiple vertebra in a desired alignment as stated by Parker. Accordingly, the teachings of Parker do not reasonably suggest a non-locking polyaxial bone screw, but instead suggest a construct that fully

locks to prevent movement of rod relative to the receiver head as well as movement of the receiver head relative to the bone screw. Such a construct fails to meet the limitation of the claims.

The teachings also reasonably suggest that, while not shown, Parker's pedicle screw includes an insert between the rod and the head of the bone screw that compresses to lock the receiver head relative to the rod. Parker explains that the "polyaxial head 115 includes a floating saddle 112 where the polyaxial screw head 110 articulates, giving the polyaxial screw shank 105 polyaxial capability." Parker at para. 0019 (emphasis added). Reference 112, however, merely points to the spherical cavity that seats the screw head. It is thus unclear what is meant by the term "floating saddle." However, Parker continues on to state that "[t]he receiver 115 may contain features to allow for mechanical assistance in seating the rod into the receiver 115. These features are well known in the art and will not be further discussed." *Id.* These mechanical features well known in the art include inserts or saddles that sit on top of the screw head and seat the rod to allow the insert or saddle to be compressed by the rod thereby locking the screw head relative to the receiver. Biedermann and Schlapfer, relied on by the Examiner, both teach such inserts or saddles. It is thus believed that Figure 1 of Parker fails to include the details of the insert or saddle because such features are "well known in the art" and because the primary object of the invention is directed to the anti-splaying feature located in the upper portion of the receiver. Accordingly, a person skilled in the art would not interpret Parker as teaching a pedicle screw having a non-locking polyaxial bone screw. Rather, they would interpret Figure 1 as simply lacking the details of the insert or saddle mentioned in the specification.

*b. Parker Is Not Enabled If The Examiner's Interpretation Is Applied*

Parker further reasonably suggests that the pedicle screw includes an insert because Parker's screw would not be enabled without an insert.

To serve as an anticipating reference, the reference must enable that which it is asserted to anticipate. "A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003). See *Bristol-Myers Squibb v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368, 1374, 58 USPQ2d 1508, 1512 (Fed. Cir. 2001) ("To anticipate the reference must also enable one of skill in the art to make and use the claimed invention."); *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996) ("To anticipate a claim, a

reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.”).

*Elan Pharm., Inc. v. Mayo Found.*, 346 F.3d 1051, 1054 (Fed. Cir. 2003). Parker’s construct is not enabled if Figure 1 is interpreted as disclosing a non-locking polyaxial bone screw because without an insert, the device cannot be assembled. As shown in Figure 1, the head (110) of the bone screw sits within a spherical cavity. While Figure 1 illustrates a cross-sectional view, as partially shown in Figure 2 the receiver head includes a circular opening in the distal-most end thereof that leads into the spherical cavity. The circular opening is non-expandable due to its circular shape, and it necessarily must have a diameter that is less than a diameter of the head of the bone screw in order to retain the head therein. As such, the head of the bone screw cannot be inserted through the circular opening, i.e., bottom-loaded. The device also cannot be assembled during manufacturing to position the bone screw within the spherical cavity because the bone screw must be driven into bone. If the receiver head truly lacks an opening for accessing the bone screw, as illustrated in Figure 1, then the bone screw would have to be driven into bone and the receiver head subsequently attached to the bone screw. However, this is impossible since the circular opening prevents passage of the screw head therethrough. Thus, while an opening and insert are not illustrated in the drawings of Parker, the only possible way to seat the head of Parker’s screw within the circular cavity would be to insert the shank of the bone screw through the proximal end of the receiver and through an opening in the portion of the receiver that separates the rod-seating cavity from the spherical cavity that seats the head of the bone screw. Since the opening would have to have a diameter that is larger than a diameter of the head of the bone screw to allow the head to pass therethrough and be seated within the distal spherical cavity, an insert or saddle would need to be inserted into the receiver head and seated on top of the head of the bone screw to retain the receiver head on the bone screw. The saddle or insert is also needed to provide the structure that is illustrated, albeit without the necessary details.

Accordingly, Parker cannot reasonably be interpreted as teaching a non-locking polyaxial bone screw construct, as required by independent claims 1 and 24. To the contrary, the specification suggests a construct having an insert or saddle that locks the bone screw relative to the receiver when the rod is locked within the received. Parker’s device is also not enabled under the Examiner’s interpretation, thus further precluding such an interpretation of Figure 1 of Parker.

c. *Biedermann Fails To Remedy The Deficiencies Of Parker*

As noted above, Parker is the primary reference in the obviousness rejection, however the Examiner concedes that Parker lacks the opening of claims 1 and 24 and argues that it would have been obvious to modify Parker to include such an opening using the teachings of Biedermann.

Biedermann, however, is equally deficient, as Biedermann lacks an opening defined by a U-shaped receiver member. While it is true that Biedermann discloses a central bore (17), the central bore (17) is defined by a pressure element (13), not by the receiver part (6) as required by claims 1 and 24. *See* Biedermann at FIG. 3. Thus, if one were to combine Parker and Biedermann, they would simply add a pressure element (i.e., an insert), not just an opening, to Parker. Such a combination would not result in the claimed invention because an insert will necessarily lock the screw head relative to the receiver.

d. *It Would Not Have Been Obvious To Modify Parker to Include an Opening*

It further would not have been obvious to a person having ordinary skill in the art to modify Parker to include an opening between the proximal cavity that seats the rod and the distal cavity that seats the head of the bone screw.

As explained above, the Examiner relies on Biedermann to teach a passageway (17) too small to allow the spinal rod to pass to sufficient to allow a screw driver to engage the bone-engaging member. The Examiner asserts that it would have been obvious to add the passageway to allow the bone-engaging member to be pre-assembled to the U-shaped receiver member. This assertion, however, is specifically contrary to the Examiner's proposed interpretation of Figure 1. If Parker is interpreted as teaching a construct in which the rod can be locked in the receiver head without locking the receiver head relative to the bone screw, then Parker's construct cannot have any insert or saddle therein and instead must be constructed as shown in Figure 1. As such, the bone screw would need to be bottom-loaded into the receiver head, i.e., the head of the bone screw would need to be inserted into the distal circular opening in the receiver head to be seated within the spherical cavity. While bottom-loading of the screw into the receiver head is impossible for reasons explained above, such bottom loading would simply eliminate the need for an opening to allow a screw driver to engage the bone-engaging member. The surgeon could simply drive the screw into bone and subsequently apply the receiver head to the screw. The Examiner cannot interpret Parker as having a

bottom-loading bone screw, and at the same time argue that it would have been obvious to modify Parker to add an opening for driving the bone screw into bone. There is just no need for an opening with a bottom-loaded screw.

Accordingly, a person having ordinary skill in the art would not modify Parker to include an opening, as suggested by the Examiner.

e. *It Would Not Have Been Obvious To Modify Parker to Have a Flat-Headed Screw and To Position the Rod Within the Distal Cavity*

As discussed above, the Examiner further admits that Parker fails to teach an opening having a size that allows a portion of a spinal fixation element to extend into the distal cavity but prevents passage therethrough of the spinal fixation element seated in the proximal recess, as further required by claims 1 and 24. The Examiner relies on Schlapfer to remedy this deficiency of Parker, arguing that it would have been obvious to further modify Parker to lower the rod such that it is positioned within the distal cavity, and to make the screw head flat (which is required to make room for the rod) “in order to provide an equivalent means of supporting a spinal rod on a polyaxial screw with predictable results.” Applicants disagree.

At the outset, Schlapfer does not have any teachings relating to the position of the rod or any advantages thereof that would motivate a person having ordinary skill in the art to make the modification proposed by the Examiner. Schlapfer merely illustrates a rod that has a portion that extends into the distal cavity, but does not even mention the illustrated location of the rod or any advantages of such positioning. The only reason Schlapfer’s rod extends into the distal cavity is because, like Biedermann, Schlapfer has an insert that seats the spinal rod. The insert is sized to provide the proper compression on the screw head to lock both the rod and the screw head relative to the receiver head. If a person having ordinary skill in the art were to modify Parker in view of the teachings of Schlapfer, they would simply add an insert that seats a rod as positioned. Such a modification would not result in the claimed invention.

More importantly, even if the size of Parker’s opening is increased, as suggested by the Examiner, such a modification would not result in the rod extending into the distal cavity. The size of the opening is irrelevant to the location of the rod. The opening is merely a circular opening in the receiver head that the rod extends across. The axial height of the rod relative to the receiver height is determined by the depth of the U-shaped cut-outs in the sidewalls of the receiver head that seat the

rod. The only way the rod would extend into the distal cavity in Parker would be if the depth of the U-shaped cut-outs in the sidewalls of the receiver head were increased to allow the rod to extend through the receiver head at a position that is below the location of the opening. There is no teaching in any reference cited by the Examiner to make such a modification, and thus even if Schlapfer and Parker could be combined, the combination would not result in the claimed invention.

Applicants further note that it would not have been obvious to flatten the screw head of Parker, which is necessary to allow the rod to extend into the distal cavity. Such a modification would disadvantageously limit polyaxial movement of the bone screw relative to the receiver head. As explained above, the only reason Schlapfer's rod extends into the distal cavity is to provide the proper compression between the components to lock the entire construct. If Parker lacks an insert, as asserted by the Examiner, then there is simply no need to provide such compression. Lowering the rod would only interfere with free polyaxial movement of the screw and would provide no advantage to Parker's construct.

Accordingly, the combination of references fails to teach or even suggest the claimed invention, and therefore independent claims 1 and 24, as well as claims 6, 7, 10-11, 26, 27, 29-33, and 35 which depend therefrom, therefore distinguish over the prior art and represent allowable subject matter.

**3. *The Combination of Parker, Biedermann, and Schlapfer does not Render Obvious Claims 12, 17-19, 21-23***

Independent claim 12 is somewhat similar to claims 1 and 24 in that claim 12 requires a fastening element that, when mated to the U-shaped receiver member, will lock the spinal fixation element to the spinal anchoring device while allowing free movement of the U-shaped receiver member relative to the bone-engaging member, i.e., claim 12 requires a non-locking polyaxial screw. Claim 12 is also similar to claims 1 and 12 in that it requires that a portion of the spinal fixation element extend into the distal portion of the cavity that seats the head of the bone-engaging member. Accordingly, for all of the same reasons discussed above with respect to claims 1 and 24, claim 12 distinguishes over Parker, Biedermann, and Schlapfer and represents allowable subject matter.

Claim 12 further distinguishes over the cited prior art because claim 12, unlike claims 1 and 24, recites that the proximal and distal portions of the cavity in the U-shaped receiver member are spaced apart by *opposed protrusions* defined by the U-shaped receiver member. None of the cited

references teach or even suggest opposed protrusions that separate proximal and distal portions of the cavity.

According to the Examiner's interpretation, Parker does not have any opening that separates the cavity in the receiver head into proximal in distal portions, and thus necessarily lacks the claimed opposed protrusions. Biedermann and Schlapfer each have an opening, albeit formed in an insert and not defined by the U-shaped receiver member. Regardless, Biedermann and Schlapfer both lack the claimed *opposed protrusions*. The opening in the inserts of Biedermann and Parker is entirely circular in shape and thus could only be considered as forming a single protrusion. Biedermann and Parker simply lack anything that can be considered to be *opposed* protrusions.

Claim 12, as well as claims 17-19 and 21-23 which depend therefrom, therefore distinguish over Parker, Biedermann, and Schlapfer and represents allowable subject matter.

#### **IV. New Claims**

##### **A. Claim 36**

As noted above, new claim 36 corresponds to claim 1, as amended in Applicant's response filed on September 19, 2007. Accordingly, Applicants assume the Examiner's rejection of claim 1, as set forth in the Office Action mailed on December 10, 2007 and maintained in the Advisory Action mailed February 26, 2008, will be applied to new claim 36. Applicants thus address that rejection herein.

Claim 1 as pending on September 19, 2007 (now new claim 36 currently pending) was rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Parker in view of Biedermann. Claim 1 as pending on September 19, 2007 (now new claim 36 currently pending) was also rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Parker in view of U.S. Patent No. 5,690,630 ("Errico"). Applicants continue to disagree with these rejections.

##### **1. *Claim 36 Distinguishes Over Parker and Biedermann***

Claim 36 distinguishes over Parker and Biedermann for all of the same reasons discussed above in Section III.A.2.a, namely because Parker cannot reasonably be interpreted as teaching a non-locking polyaxial bone screw construct, as required by independent claim 36. To the contrary, the specification suggests a construct having an insert or saddle that locks the bone screw relative to the receiver when the rod is locked within the received. Parker's device is also not enabled under the

Examiner's interpretation, thus further precluding such an interpretation of Figure 1 of Parker. New claim 36 therefore distinguishes over Parker and Biedermann and represents allowable subject matter.

## 2. *Claim 36 Distinguishes Over Parker and Errico*

Claim 1 distinguishes over Parker for the same reasons previously discussed in Section III.A.2.a. Errico does not remedy the deficiencies of Parker. Errico is merely cumulative of Biedermann as Errico, like Biedermann, is directed to a system that utilizes an insert or locking collar to lock the screw head relative to the receiver head. Thus all of the reasons discussed above in Sections III.A.2.c, III.A.2.d, and III.A.2.e with respect to Biedermann apply equally to Errico. New claim 36 therefore distinguishes over Parker and Errico and represents allowable subject matter.

## B. **Claim 37**

New claim 37 depends from new claim 36, and as noted above, new claim 37 includes language added to claim 1, as amended in Applicant's response filed on June 10, 2008. This language was not effective in overcoming the Examiner's rejections, and thus the Examiner maintained the rejection of claim 1 over (1) Parker and Biedermann, and (2) Parker and Errico. Applicants disagree with these rejections for the same reasons set forth above with respect to claim 36. Claim 37 further distinguishes over Parker, Biedermann and/or Errico for the following additional reasons.

Claim 37 recites that the opening is defined by the U-shaped receiver member. None of the references teach or even suggest an opening that is defined by the U-shaped receiver member. Parker simply lacks an opening. The remaining references all include an insert that defines the opening, and thus all lack any opening that is *defined by the U-shaped receiver member* and that separates the distal cavity and the proximal recess. The Examiner simply cannot rely on an opening in an insert to modify Parker without also adding an insert to Parker. The only reason the opening in the insert is provided is because devices with an insert require the bone screw to be top-loaded (i.e., inserted through the proximal end of the receiver head), and thus the insert is needed to apply compression to the screw head and the opening is needed to allow access to the screw head. If the Examiner's interpretation of Parker is applied, Parker is bottom-loading and simply lacks the need for any opening. The bone screw is driven into bone prior to applying the receiver head to the bone screw, and thus there is no need for an opening in the receiver head.

Accordingly, claim 37 further distinguishes over the cited references and represents allowable subject matter.

***Conclusion***

Applicants submit that all claims are in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

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Respectfully submitted,

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